K121250

Traditional 510(k)
Alco-Screen® 02

SEP 12 2012

Section 5: 510(k) Summary

Assigned 510(k) number:

Company:	Chematics Inc. PO Box 293 4519 Highway 13 South North Webster, IN USA 46555 Phone: 574-834-2406 Fax: 574-834-7427
Contact:	Carl Reynolds Phone: 513-265-6257 574-834-2406 Email: creynolds@chematics.com
Date Prepared:	March 23, 2012
Proprietary Name:	Alco-Screen® 02
Classification Name:	Alcohol test system
Classification:	21 CFR 862.3040, Class II, Product Code DIC
Predicate Devices:	K894001 Orasure Technologies Inc, QED A150 Saliva Alcohol Test
Device Description:	ALCO-SCREEN® 02 is a visually read qualitative test for the detection of alcohol using saliva. The test strip indicates the relative Blood Alcohol Concentration (BAC) at 0.02%. The device consists of a box of 24 individually packaged single test strips each designed for single use and to be disposable, and instruction for use.
Intended Use:	The ALCO-SCREEN® 02 is a qualitative screening test used to detect the presence of ethyl alcohol in human saliva. The test detects relative Blood Alcohol Concentrations (BAC) greater than or equal to 0.02%. Results are used for the diagnosis of alcohol intoxication. For in vitro diagnostic use. The assay is a disposable test for one-time use.

Technological Comparison to Predicate Device:	Alco-Screen® 02 is similar to the predicate device. Both tests can be used to qualitatively measure alcohol in human saliva. Additionally, both employ enzymatic oxidation of alcohol and chromogenic reaction methodology to produce a visually interpreted color change. Performance test results confirm that design differences do not pose new issues of safety or effectiveness.
Performance Testing:	The performance characteristics of Alco-Screen® 02 were determined by conducting precision and reproducibility studies, analytical specificity studies, stability studies, and field use studies with an evidentiary device. Results demonstrate that Alco-Screen® performs as intended and meets all established specifications.
Conclusion:	Based upon the design, technology, performance, and intended use, Alco-Screen® 02 is substantially equivalent to the predicate device currently marketed under the Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 12 2012

Chematics, Inc.
c/o Carl Reynolds
Regulatory Affairs Specialist
P.O Box 293
4519 Highway 13 South
North Webster, IN 46555

Re: k121256
Trade/Device Name: Alco-Screen 02 Saliva Alcohol Test
Regulation Number: 21 CFR 862.3040
Regulation Name: Alcohol Test System
Regulatory Class: Class II
Product Code: DIC
Dated: August 13, 2012
Received: August 16, 2012

Dear Mr. Reynolds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121256

Device Name: Alco-Screen® 02 Saliva Alcohol Test

Indications for Use: The ALCO-SCREEN® 02 is a qualitative screening test used to detect the presence of ethyl alcohol in human saliva. The test detects relative Blood Alcohol Concentrations (BAC) greater than or equal to 0.02%. Results are used for the diagnosis of alcohol intoxication. For in vitro diagnostic use. The assay is a disposable test for one-time use.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121256